APPARATUS FOR COMPACTING POWDER

FIELD OF THE INVENTION

This invention concerns apparatus for compacting a powder. More particularly, though not exclusively, this invention concerns apparatus for producing a dosage form comprising a compacted powder, which powder includes a medicament and/or a dietary supplement, such as a vitamin.

BACKGROUND TO THE INVENTION

Dosage forms comprising compacted powders including pharmaceuticals, vitamins and/or other dietary supplements for human ingestion are well known. Additionally, compacted powder dosage forms are used with industrial and domestic detergents and the like.

Powders or mixtures of powders required to be compacted in various applications have variable physical properties. For example, one powder may differ from another in terms of one or more of volume, density, flowability and compressibility. Such physical differences cause problems in powder compaction devices or presses where dosing cavities are required to be part filled or over filled and/or the compacted product deviates from the optimal the size or mass.

Tablets are a common type of a dosage form and various means for improving their properties have been tried. Current methods for coating tablets, such as pharmaceutical tablets, include the using of acelacoaters or pan coaters, which spray e.g. low molecular weight HPMC grades onto tablets so imparting a surface layer, which is uniform and smooth, but opaque and low gloss. It is possible for the tablets to have embossed lettering on them. This method of coating tablets is however time consuming and requires a high level of expertise to produce satisfactory results. Production complications such as tablet twinning are common, where two tablets become attached to one another during the spray coating operation. In addition to these problems it is necessary to compact the tablets under relatively high pressures so that they do not disintegrate during the coating process. This high level of compaction

can have an adverse effect on the disintegration and dissolution rates of active ingredients contained within the capsule, for example, leading to a delay in the release of a drug to a patient, whilst the tablet slowly dissolves in the stomach of the patient.

An alternative to spray or pan coating is to use two-piece hard capsules. These are produced by a dipping process, typically a HPMC solution is used, producing half shells which interlock and thus produce an enclosed capsule. These capsules are typically opaque but glossy, and cannot have any form of embossment, as this would interfere with the overlap interlocking process. The nature of the capsule dictates that there will always be an airspace above the powder fill level. Additionally, it is not possible to compact the powder into these tablets, and this so limits the quantity of powder which can be encapsulated. It follows that this lack of compaction can, effectively reduce the amount of e.g. medicament which can be encapsulated. The existence of the air space in the capsule and lack of compaction of the powder contained within the capsule leads to a capsule that is inevitably larger than necessary.

It has also been found that, after manufacture and/or sale of two-piece hard capsules, the capsules can be easily and illegally interfered with, as it is possible to separate the two halves of the capsule and tamper with its contents and replace the two halves back together without there being any obvious change in the capsule's external appearance such to suggest to the user that there was anything wrong with the capsule. This means that it can be difficult to detect capsules which have had their contents tampered with. HPMC and certain other non-gelatin materials are suitable for ingestion by humans, so delivery capsules with gelatin walls find potential use as ingestible capsules, e.g. for the delivery of accurately metered doses of pharmaceutical preparations and dietary supplements, as a possible replacement for gelatin based capsules. Conventional tablets have already been enrobed. See for example WO-A-02098394.

In EP-B-0493489, compacted powder cores comprising a medicine are enrobed with a biodegradable and/or water soluble film, for example a non-gelatin film, such as hydroxypropyl methyl cellulose (HPMC), to produce dosage forms comprising encapsulated bodies of compacted powder.

WO-A-03096963 discloses a method for the preparation of a compacted powder slug enrobed within two separate overlapping half coatings of a film of e.g. HPMC. The method includes forming a lining of a first film in a piston chamber, dispensing a free flowing powder into the chamber from a dosing means and then, with a piston, compacting the powder in the film lined chamber to form a powder slug partially enrobed within the first film. The remaining uncoated portion of the compacted powder slug is then enrobed within a second film coating, which overlaps and seals with the first film coating. The above type of insitu-compaction technique is particularly useful where it is desired to compact the powder to a lesser extent than in conventional hard tablet presses. Problems with powder property variations apply in these moderate compaction techniques just as they do in conventional tablet pressing techniques.

Dispensing the powder into the piston chamber can produce dust, which dust may affect the efficient functioning of the coating machinery and/or cause a health hazard to workers who may become exposed to the dust (which is especially problematical if the dust comprises particles of a pharmaceutical).

The present invention seeks to provide an improved powder compaction apparatus.

SUMMARY OF THE INVENTION

The invention, in its various aspects is as set out in the accompanying claims.

According to a first aspect of the present invention, there is provided an apparatus for compacting a powder comprising:

i) a compaction chamber;

ii) dosing means adapted to dispense a powder through said entrance and into said compaction chamber; and

iii) a powder supply;

wherein said dosing means comprises a plurality of juxtaposed components between which components is formed a dosing cavity for receiving powder from the powder

supply and dispensing powder to the compaction chamber, wherein the volume of the dosing cavity and at least the cross-sectional area of the cavity perpendicular to the direction of flow of the powder when the powder is dispensed into the compaction chamber are variable by adjustment of the respective positions of the juxtaposed components.

In accordance with another aspect of the present invention, there is provided an apparatus for compacting a powder, comprising:

a powder supply conduit (40);

a compaction chamber;

dosing means (20) comprising a plurality of interleaved components defining dosing cavity for accommodating powder en route from the powder conduit to the compaction chamber, said dosing means being moveable relative to said supply conduit and said compaction chamber, such that the dosing cavity can adopt a powder receiving position in communication with said powder supply conduit and a powder dispensing position in communication with said compaction chamber; and

powder compaction means capable of compacting powder in said compaction chambers, wherein, in use, internal spaces of the apparatus through which the powder passes from said supply conduit to said compaction chamber comprise a closed system.

In accordance with another aspect of the present invention, there is provided an apparatus for compacting a powder comprising:

a powder supply;

a compaction chamber;

dosing means (20; 50) comprising a dosing cavity defined by a plurality of juxtaposed components moveable in relation to one another such that the volume of the dosing cavity is adjustable so as to be greater when receiving powder from the powder supply than when dispensing powder to the compaction chamber.

Apparatus as claimed in claim 10, wherein the compaction chamber is disposed laterally from and below the powder supply, such that said dosing cavity can be translated from a first position for receiving powder from the powder supply substantially under the force of gravity and a second position for dispensing powder to the compaction chamber.

In accordance with another aspect of the present invention, there is provided an apparatus for compacting a powder comprising:

i) a die including a piston chamber having an entrance for receiving a piston;

ii) dosing means adapted to dispense a free flowing powder through said entrance and into said piston chamber; and

iii) a piston having a cross-sectional area reciprocal with the piston chamber and being adapted such that in use the piston enters said chamber, thereby to compact any powder in said chamber, and then exits said chamber;

wherein said dosing means comprises a plurality of juxtaposed components between which components is formed a dosing cavity for receiving and dispensing powder, wherein the volume of the cavity and at least the cross-sectional area of the cavity perpendicular to the direction of flow of the powder when the powder is dispensed into the piston chamber are variable by adjustment of the respective positions of the juxtaposed components such that when powder is received into the dosing cavity said volume and cross-sectional area is greater than when powder is dispensed from said cavity into said piston chamber.

In one embodiment of the present invention, the dosing means comprises at least two, though two are preferred, juxtaposed plates with interleaving parts which together form a dosing cavity.

The dosing means is movable between a first position, where the powder is received into the dosing cavity, and a second position, where the powder is dispensed from the dosing cavity into the piston chamber of the die.

Preferably, the components of the dosing means are adjustable such that in the first position the dosing cavity is capable of receiving a specific volume of powder, which powder has a known composition and bulk density. When the dosing means is moved into the second position, the dosing cavity is over the entrance to the piston chamber and the powder is capable of being dispensed into the chamber. In this second position, the juxtaposed components are adjusted until the cross-sectional area of the dosing cavity is reduced to the point where it is substantially the same as the cross-sectional area of the piston chamber, thereby to ensure that substantially all of the powder is dispensed into the chamber.

After all or a major proportion of the powder has been dispensed into the piston chamber it is compacted by the action of the piston moving into the chamber.

The dosing means may be removed before the piston is permitted to enter the piston chamber. However, in a preferred embodiment, the dosing means remains in position over the entrance to the piston chamber and the piston enters the chamber by passing through the dosing cavity (the components of the dosing means having been adjusted to provide the cavity with a cross-sectional area substantially the same as the piston chamber).

Preferably, the apparatus comprises a plurality of dies and pistons and the dosage means comprises sufficient components to provide a plurality of interleaving parts which form a dosage cavity for each piston and die. The dosage means may comprise two plates with multiple interleaving parts. For example, one plate may comprise a plurality of slots into which a plurality of fingers on the other plate may slide, wherein a plurality of dosage cavities are formed between the end of the fingers and the base of the slots. In this way, the apparatus of the invention may be employed to mass produce compacted powders.

The apparatus of the invention is advantageously employed to reduce the amount of dust formed in powder compacting processes.

Whilst the invention is preferably employed in the preparation of coated or uncoated compacted powders comprising pharmaceutical and/or diet supplements, the invention

is not so limited and may be used in the formation of any coated or uncoated compacted powders. The apparatus of the invention is preferably used in any of the four methods of forming encapsulated compacted powder slugs disclosed in WO-A-03096963, the disclosure of which is included herein by way of reference.

LIST OF DRAWINGS

This invention is now further described in detail, by way of example only, with reference to the drawings in which:

Fig. 1 shows the various stages of a powder compaction/enrobing process disclosed in WO-A-03096963;

Fig. 2 shows the various stages of another powder compaction/enrobing process disclosed in WO-A-03096963;

Fig. 3 shows the various stages of yet another powder compaction/enrobing process disclosed in WO-A-03096963;

Fig. 4 shows the various stages of yet another powder compaction/enrobing process disclosed in WO-A-03096963;

Fig. 5 is a perspective view of a preferred apparatus in accordance with the present invention;

Figs. 6 to 9 are sectional views through the vertical center line of the preferred apparatus shown in Fig. 5, and depict the four stages of operation of the apparatus;

Fig.10 is a sectional view through the vertical centre line of the preferred apparatus, showing a powder supply conduit;

Fig. 11 shows an embodiment of dosing mechanism capable of high volume productions;

Fig. 12 shows the embodiment of Fig. 11 mounted on a die 62;

Figs 13A & 13B show an agitator which may be used with embodiment of Fig. 11;

Figs 14A & 14B show an assembly for a powder compaction apparatus incorporating the dosing mechanism of Fig.11.

DESCRIPTION OF EXEMPLARY EMBODIMENT

FIG. 1 shows the mechanism of the basic steps of powder compaction and enrobement via steps a-l of WO-A-03096963:

a. A first film (1) is laid upon a die (2). Lower piston (3), slideable in piston chamber (4), incorporates vacuum port (5).

b. Film (1) is drawn into and lines chamber (4) by vacuum created by vacuum port (5), to form a pocket shape.

c. A quantity of powder (6), delivered to the entrance of the chamber (4) in a dosing means (20) comprising a single plate having a dosing cavity (21) therein, is introduced over the pocket of film. Upper piston (9) moves downward, passing through the dosing cavity, towards the lower piston (3), forcing the powder (6) into the chamber (4) and compressing it.

d. A compacted powder slug (7) resulting from the completion of step c remains in the chamber (4) when the upper piston (9) is withdrawn.

e. Cutting of film by the introduction of cutting tool (10) to form an isolated semi enrobed slug of compacted powder.

f. Lower piston (3) begins to move upwards, thereby also urging compacted powder slug (7) upwards.

g. Lower piston (3) comes to rest, positioning compacted powder slug (7) proud of die (2).

h. Introduction of a second film (8) over die (2) and also loosely stretching over compacted powder slug (7).

i. Second vacuum is applied drawing second film (8) around and closely in association with the upper portion of compacted powder slug (7), second film (8) thereby wrapping itself around the upper part of the compacted powder slug (7).

j. Cutting tool (12) descending and trimming off excess unwrapped film from powder slug (7).

k. Fully enrobed powder slug, has been ejected from chamber (4) by the further upward movement of lower piston (3) and has the loose ends of the films ironed and sealed by irons (13).

l. Shows a fully enrobed tablet with ironed seams.

FIG. 2 depicts a variation of the basic process described by FIG. 1.

Steps a1 and b1 show a second pre-formed film pocket, formed by a second vacuum forming pocket (14) being lowered onto the die immediately above a partially enrobed powder slug as shown in step f of FIG. 1. Once the opposing film pocket is in position lower piston (3) moves upwards thus pushing compacted partially enrobed powder slug also upwards and into the cavity of the second pre-formed film pocket, thus capping the partially enrobed powder slug to form a fully enrobed capsule, enrobed by two pockets of film. The capsule is then released, trimmed and ironed as mentioned previously.

FIG. 3 depicts a further variation of the basic process described by FIG. 1.

Step a2 shows a powder slug as in step f of FIG. 1, and like FIG. 2 a second pre-formed film pocket is introduced, but this time it is a shallow pocket, formed by a second shallow vacuum forming pocket (15), such to only coat the top of the powder slug and to form a seal at the circumference of the very edge of the cylindrical portion of the powder slug. Steps a2-d2 show this revised process. This process gives rise to a capsule with a different type of seal which gives rise to different properties in the capsule.

FIG. 4 depicts another variation of the process described by FIG. 1.

However the basic process is essentially duplicated to form a capsule which contains two distinct half doses of powder. The basic process as described in FIG. 1 is carried out up to step f, in duplicate, which is basically steps a3-c3 in FIG. 4. The main differences at this point in FIG. 4, are that the two opposing pockets filled with compacted powder (16,17) are half size in depth, and the top of the powder slugs are essentially flat, rather than rounded. Step c3 may include the laying down of an intermediate film on the surface of the half slug. Steps d3-f3 show the bringing together of 2 half slugs to form a single capsule, comprised of 2 parts. Step g3 shows a compartmentalized capsule. The advantages are at least 2 separate doses of active ingredients can be incorporated into 1 capsule, under perhaps different compaction pressures etc. This gives rise to further flexibility and options as to the performance of the new dosage forms.

Fig. 5 shows a preferred embodiment of the apparatus of the present invention. The apparatus comprises a die (2), including a lower piston (3), incorporating a vacuum port (not shown), slideable in piston chamber (4). Dosing means (20) comprises two juxtaposed plates (22, 23) which interleave to form dosing cavity (21). The cross-sectional area of the cavity (21) (and consequently the volume of the cavity as well) may be increased or decreased by moving plate (22) relative to plate (23) in direction A or B, respectively. The dosing means (20) may be moved so that the dosing cavity (21) is away from or over the entrance of the piston chamber (4) by sliding it in direction C or D, respectively. When the dosing cavity is over the entrance of the piston chamber, upper piston (9) passes through the dosing cavity (21) to enter the piston chamber (4). The piston (9) is aligned over the die (3) by means of a guide sleeve (24).

In use, the apparatus of Fig. 5 is aligned and operated as illustrated in Figs. 6 to 9. Upper die (9) and guide sleeve (24) are shown orientated above the entrance of piston chamber (4) of die (2). Lower piston (3) is in its lowered position, forming the bottom of piston chamber (4).

In Fig. 6, the upper piston (9) is shown retracted in the guide sleeve (24), away from the piston chamber (4). Dosing means (20) is located at position C, with the bottom of the dosing cavity being closed by its contact with the surface of die (2). The plates (22, 23) which form the dosing means (20) are aligned at position A, to provide a dosage cavity (21) of a volume required for receiving a specified amount of powder. In this position, the relative positions of the plates (22, 23) provide a cavity (21) that is larger than the finished volume of the compacted powder slug, thereby accommodating the larger volume of the lower bulk density powder.

The dosage cavity (21) may be overfilled with powder, and any excess powder removed as the dosing means is slid into position D, with the dosing cavity over the entrance of the piston chamber (4), as shown in Fig. 7.

As shown in Fig. 8, when the cavity (21) is over the piston chamber (4), powder is urged to fall into the piston chamber as the plates (22, 23) are drawn together to position B. Typically, this occurs by further movement of plate 22 towards plate 23, which remains stationary over the piston chamber. As the plates (22, 23) are drawn together, thereby reducing the volume and the cross-sectional area of the cavity, any powder that sits on the surface of the die is thereby swept into the piston chamber. Movement of the plates (22, 23) is stopped when the cross-sectional area of the cavity (21) is substantially the same as the cross-sectional area of the chamber (4).

As shown in Fig. 9, the upper piston (9) is pushed down through the dosing cavity (21) and into the piston chamber (4). The powder in the chamber is subjected to compressive forces which compact the powder into a slug or tablet.

Once the powder has been compacted, the piston (9) is retracted back into the guide sleeve (24) and the dosing means (20) slid back into position C.

FIG.10 shows the preferred apparatus in substantially the same state as Fig. 6 albeit that a powder supply conduit (40) is shown abutting the plates (22) and (23) from above. The powder supply conduit (40) extends between a powder hopper or similar storage receptacle (not shown) and dosing cavity (21).

In use, powder is supplied to the dosing cavity (21) via the powder supply conduit (40), by any suitable mechanism. The powder charge in the dosing cavity (21) is transferred to the piston chamber as the plates (22,23) are slid from position C to position D and the plates (22,23) are drawn together. The powder is then compacted as described with reference to Fig.9.

Figs. 11 and 12 illustrate a preferred embodiment of dosing means adapted for use on a machine with an array of adjacent powder compaction chambers. Such machines are used to manufacture large volumes of products and may have many such arrays.

The powder dosing and compaction unit of Fig. 11 is an assembly of parts that is mounted above the die 62 and is connected to the bulk powder supply. It has two key functions:

a. to accurately control the quantity of powder that is placed into each cavity.

b. to remove excess powder and compress the powder in piston cavities.

Where the compacted product is coated or enrobed this unit may also cut the film that has been formed into the cavities.

The quantity of powder is controlled by a dosage mechanism (50), which consists of two slideably interleaved finger plates (52), (53) that fit together as shown in Fig. 11 to create dosing cavities (54) of adjustable sectional area. The depth of engagement of these two plates (52), (53) thus controls the volume of the cavities. The assembly of these two plates is slideably mounted such that the cavities can be moved horizontally on die (62) between position D, where the powder is compressed into a slug or tablet form, see Fig. 12. The compaction chambers below plate (53) are not shown on Fig. 12.

To ensure that the cavities in the finger plates completely fill with powder there is an agitator (72) mounted above the fill area within the powder hopper. This consists of a shaft with "vanes" of the form shown in Figs.13A and 13B. This agitator is not a spiral screw. When the shaft is rotated the vanes agitate the powder gently without compressing it and thus promote a consistent supply of free flowing powder.

Fig. 14A shows the agitator (72) mounted in a housing (70) which is above the dosing cavities (54). With reference to Fig.14A and 14B compression of the powder is achieved by means of a row of pistons 82 that are mounted in the housing (70) above position 'D'. The pistons pass through bores formed by the finger plates (52), and the die 2 to perform compaction against a base provided from below.

In this way powder can be compacted into a series of piston chambers to generate a plurality of products simultaneously. The strokes of the compression pistons 82 are generally controlled to ensure a fixed size for the finishing slugs or tablets. A skilled person will appreciate that compaction means other than pistons, e.g. air pulses, may be used in the alternative.

The action of finger plates (52), (53) and surrounding parts corresponds generally to that described herein before with respect to Figs.5-10, with the plates (52), (53) of dosage mechanism (50) respectively, corresponding to plates (22), (23) of the dosage means (20). In this case, the plates (52), (53) are moved together such that the dosing cavities are translated to a position D above the compaction chambers and below the pistons.

From the foregoing description it will be appreciated that preferred embodiments provide a variable volume chamber adapted to cope with powders of varying physical

properties, which chamber when correctly adjusted to receive the required charge of powder causes the production of dosage forms of the required mass and size. Further, since the powder charge is supplied from the hopper to the compaction chamber entirely within a closed system (i.e. without being exposed to the surrounding environment) the amount of dust generated in use is reduced or eliminated.

The apparatus of the present invention may be used to produce coated or uncoated compacted powders. If a coating is required, the apparatus is most suitably employed in step c of the coating/enrobing processes illustrated in Figs. 1 to 4.

A skilled reader will appreciate that while the foregoing has described what is considered to be the best mode, and where appropriate other modes of performing the invention, the invention should not be limited to the various apparatus configurations or method steps disclosed herein. The invention has a broad range of applications and the various embodiments might represent a number of modifications and alternative implementations, without departing from the scope of the invention as defined in the claims.